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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,667

Applicant(s)

PETERSEN

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment filed 11/26/2001.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating incontinence or vesicoureteral reflux, does not reasonably provide enablement for preventing incontinence or vesicoureteral reflux. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. It is not known how a method/process wherein a composition is claimed can be administered to prevent incontinence or vesicoureteral reflux. The specification does not teach how an individual is diagnosed as one who would come down with the condition and to successfully prevent the occurrence. It is not known how the occurrence of incontinence or vesicoureteral reflux can be precisely predicted in a healthy subject such that the claimed composition is administered to **prevent** the development of incontinence or vesicoureteral reflux in the said patient.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

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- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples
- 7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The present invention is in the field of treating incontinence or vesicoureteral reflux by administering a hydrogel composition to a patient in need thereof.

The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent incontinence or vesicoureteral reflux before the occurrence.

The level of ordinary skill is high but only in the art of treating preventing incontinence or vesicoureteral reflux. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants. However, the amount of direction and guidance provided by the applicants is limited to treatment. The specification does not provide guidance as to how to predict the absence of incontinence or vesicoureteral reflux in a healthy subject and to predict with certainty that when the said subject would develop the

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condition. There is no teaching in the disclosure that such a prediction led to the prevention of the condition. Generally the condition is detected in a patient before commencement of treatment. There is no evidence in the specification that established correlation between the experiment and the claimed utility. See Ex parte Mass, 9 USPQ2d 1746, 1987. Thus, the quantity of experimentation required to use the method/process as claimed in the instant invention, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo experiments **prevent the occurrence of adhesion** after surgical procedure.

Treating may be used in place of "preventing".

4. Claims 3-5, 7, 8, 11, 12, 14, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 17 and 19, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 3-5, 7, 8, 11, 12 and 14 recite "preferably" and a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether

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the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3, for example, recites the a polyacrylamide weight of 15% which is a higher amount, and the claim also recites polyacrylamide weight of 10% and 7.5% which is lower statement of the previously recited limitation. This is range within a range.

Claim Objections

5. Claim 17 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 17 not been further treated on the merits.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028).

Vogel teaches a method for treating urinary incontinence by administering a pyrogen free composition and the composition comprises hydrophilic polyacrylamide or its derivatives and methylene-bis-acrylamide (abstract and column 7, lines 6-22). Although, Vogel does not refer

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to the composition as hydrogel, a composition formed from acrylamide monomer and methylene bis-acrylamide cross-linking agent is a hydrogel, because it is known that polyacrylamide monomers cross-linked with methylene bis acrylamide is a hydrogel (see Halpern et al., US 3,867,329, column 2, line 33 to column 3 line 18). Vogel is silent on the viscosity of the hydrogel composition. But one of ordinary skill in the art would know routine method of measuring/determining the viscosity of a hydrogel composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Vogel. One having ordinary skill in the art would have been motivated to prepare the composition of Vogel and administer it to treat urinary incontinence in a subject in need thereof. The expected result is a hydrogel composition comprising acrylamide and methylene bis-acrylamide for the treatment of urinary incontinence. The viscosity of the hydrogel composition of the invention does not patentably distinguish the invention over the prior art.

8. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 10, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER T600